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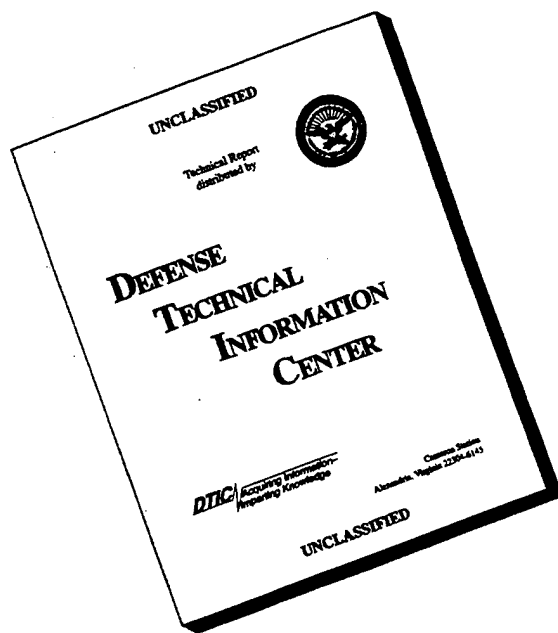
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**EVALUATION, UTILIZATION, MODIFICATION
DEVELOPMENT AND TRAINING
REQUIREMENTS OF PRE-ESTABLISHED FDA
APPROVED FIELD MEDICAL EQUIPMENT FOR
THE FAR FORWARD RESUSCITATION,
TREATMENT AND EVALUATION OF THE
CRITICALLY INJURED SOLDIER**

By

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October 1995

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FOREWORD

This research was carried out under Funding Line 1160407BB through Accession Number DN241155, this research was supported and directed through the Naval Medical Research Development Command. It was also supported by technical support from Cook Critical Care, Bloomington, IN: PROTOCOL, Beaverton, Oregon and RAP. Buena Park, CA. It was supported through the Division of Surgery at the Walter Reed Army Institute of Research.

INTRODUCTION

The application of advanced life saving procedures to the injured soldier usually occurs at the forward edge of the battle area (FEBA), where the care is usually provided by a medic. Mortality from trauma usually breaks down into: 50-60% secondary to Central Nervous System injury, 30-40% by Hemorrhage, 15-20% Airway Failure. The areas that can be improved upon in medic training and technical support include advanced fluid resuscitation, airway management and recognizing and treating identifiable traumatic injuries. In order to begin to provide advanced resuscitative care in the far forward area, either the equipment which usually is designed for an advanced provider (i.e. Physician) to utilize, must be modified or the ability to assess training regimens regarding the efficacy in the utilization of the equipment must be analyzed to assure adequate reproducibility, technical expertise and desired endpoint in regards to acceptable trauma care. While Advanced Trauma Life Support (ATLS) has set standards for the treatment of various life threatening injuries the ability of a medic to perform these tasks has not been assessed. Also the limited resources and equipment that the Special Forces medic has available in the austere special operations environment may further limit procedures that are routinely available at the battalion aid station or other far forward medical units.

By beginning at the FEBA, where the medic is the most likely individual to treat the critically injured patient, an attempt can be made to decrease battlefield casualties by providing, assessing and modifying via training and equipment modifications current problems relevant to battlefield care. The modification and design of equipment will be performed with the concept of actual care provider involved in assessing difficulties in training, relative equipment failures, and overall assessment of whether a medical device that would be standard of care in the hospital based trauma algorithm is acceptable for medic performance. Each provider will now be part of the assessment and development of the product and realistic goals for trauma care and advanced practice can be established.

METHOD

The intent was to identify problem areas in advanced medical resuscitation and care that are currently faced by the medic in the special operations community. These projects were defined and identified by the Research Coordinator for Biomedical Research, Director of the Naval Special Warfare Command. The initial four projects with very early applications included:

- Medical Equipment Transport/Medics' Bag
- Cricothyroidotomy Set
- Thoracostomy Set
- Monitoring Devices

After identification of the problem areas, a thorough search of the literature and evaluation by the Principal Investigator's of practical equipment solutions to each of the problems was completed. Those items selected for further testing were then assessed for training issues, ease of operation, medical necessity and reproducibility of procedure was completed in the laboratory situation as well as in field training exercises. This was accomplished with the goal to provide single items that met rigid criteria for application. The criteria for acceptance were: hardness, ease in technique, medic acceptability, time course for procedure, length of training, acceptable result, FDA approval, and ability to modify the equipment if necessary.

After each product was identified (See Individual Discussions), the product was modified as appropriate, packaged and then transported to the SEAL training facility at Coronado NAS for testing under field and vivarium conditions in the medics hands. This testing utilized all the above criteria prior to attempts at simulated field conditions.

A questionnaire assessing the usefulness, relevance, training and desired modifications necessary was completed by each medic tested and was utilized to further modify, package and delineate further work necessary for each product. The questionnaires also assessed prior medical training of the individuals involved in the testing and previous experience in order to determine the level of expertise necessary to complete the task.

In order to leverage the assets, a relationship was established with numerous commercial partners to provide testing material, product acquisition and training material. These included PROTOCOL, Beaverton, Oregon; Cook Critical Care, Bloomington, Indiana and RAP, Buena Park, California.

RESULTS

MEDICAL BAG

A review of the current field medical bag, rucksack and options available in the civilian sector was done. The equipment carried by the medic is in excess of that usually transported by the civilian medic secondary to the austere conditions encountered in the military and the lack of a fixed facility (ambulance, aircraft) near the site of the incident. There is a tremendous need for portability as well as development of a military unique fixed facility bag. Therefore, this project was approached from two separate directions:

FIXED FLIGHT/TRANSPORT BAG

The evacuation either aeromedically or by ground vehicle assumes that the injured soldier is somewhat stable, however lifesaving procedures and treatment may be required prior to successful evacuation to a definitive care facility or may be necessary during the transport process. This Flight Transport Bag (Figure 1) was designed to contain adequate equipment to treat six critically injured soldiers and provide surgical support in an emergency situation for two casualties with any potential battlefield or trauma injury commonly encountered. (Appendix 1) The equipment list was generated through a questionnaire circulated amongst medics, physicians, EMT's and flight nurses. It was also compared against numerous air and ground flight manifests of equipment currently utilized.

In its' full configuration this bag will provide resuscitative care and support for the total trauma casualty to include pediatric, thoracic trauma and obstetric support. The bag when totally loaded will weigh between 40-45 pounds and is easily configured to meet the individual load requirements of the medic. It also can be utilized as a single strap "fanny pack" configuration (Figure 2) to extend the support load. This bag was designed and developed through a cooperative arrangement with RAP, Buena Park, California. RAP provided the technical support in physical development and in prototype delivery and numerous modifications. The modifications were accomplished after numerous revisions and field testing at various locations.

This bag was tested during the SEAL medic training course at Coronado NAB, CA and was found after extensive evaluation to be acceptable as a fixed vehicle bag. It has also been evaluated by the Air Force Special Operations medics at Hurlbert Airfield and was noted to be acceptable as an inflight bag. The biggest shortcoming of the product was size and continually was found to be too large for routine manual carrying except in the short recovery situation. The real potential for this first level bag was in the vehicle, either the roto or fixed wing as well as in the armored ambulance. It was determined by successive evaluation to meet the requirements for advanced resuscitative care and in providing extended portable critical care. It met acceptable criteria from medics, flight nurses, physicians and EMT's.

4 Pack • Medic Set Padded

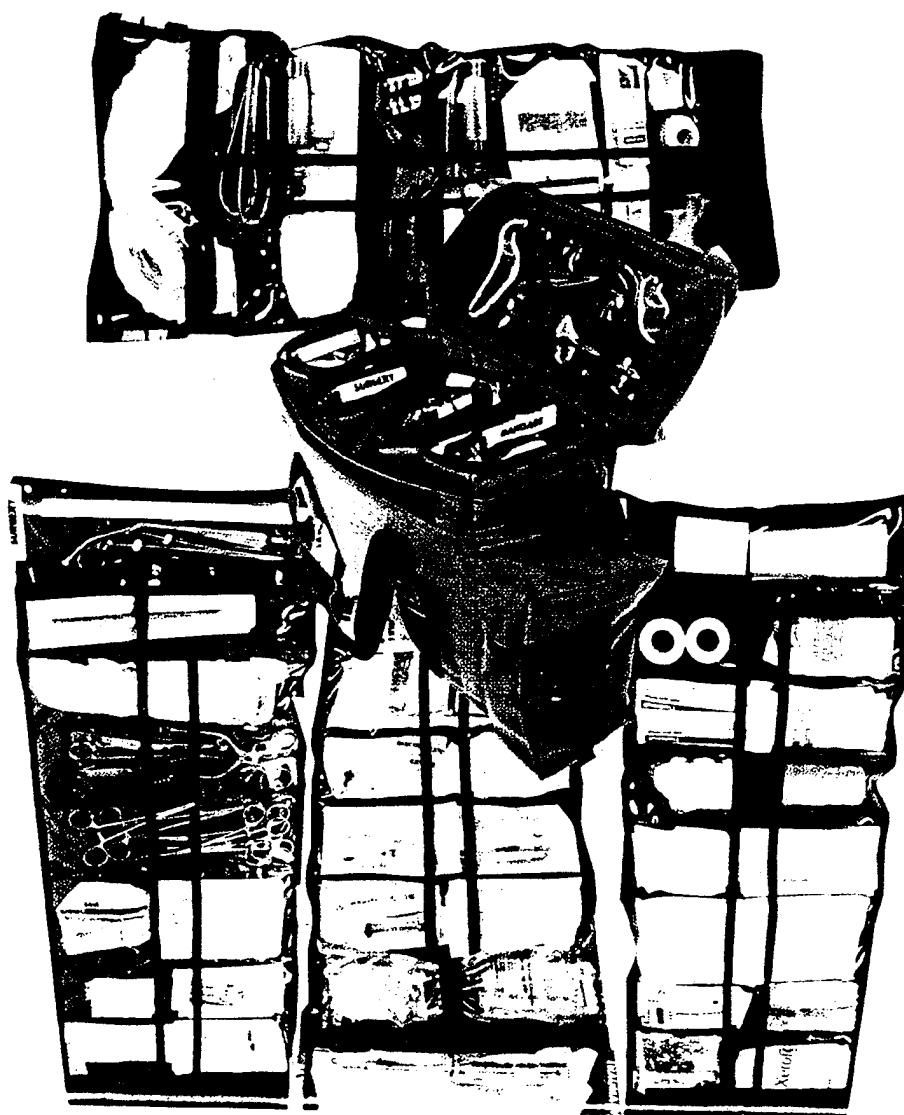


Figure 1. Fixed Vehicle Medical Bag: Six Mini-Bag version with detachable bags included



Figure 2. Internal Individual Medical Bag "Fanny Pack" Shown Deployed on Soldier

MEDICAL RUCKSACK

The second project developed into a two track project that assessed current rucksack capabilities and then totally redesigned a new combination medical rucksack that included a medical bag as a component of a standard rucksack. This project was developed jointly through the Walter Reed Army Institute of Research and a team of engineering, human factors and design faculty at the United States Military Academy, West Point, NY and encompassed over 500 man hours of work.. This was a semester long project based upon an extensive evaluation, testing and characteristics determined by QFD analysis (Course ME 494/496).

This research lead to the development and prototyping of a new advanced combination field rucksack and medical bag that provided initial resuscitative care for six soldiers assuming a worst case scenario. (Figure 3,4) . A subsidiary product was a small lightweight bag that could be hand carried and was jump capable. (Figure 5) The hand bag provided for four critical soldiers under all conditions.

These bags remain to be completely field tested, however they were assessed by the Air Force at Hurlbert Airfield and were found to be acceptable in configuration, design and compatibility with stated mission needs. The biggest problem remains that the bags will again add to the weight of the standard rucksack. This rucksack has gotten acceptable reviews for functionality however true field testing in an austere environment needs to be accomplished as the human factors are now defined.

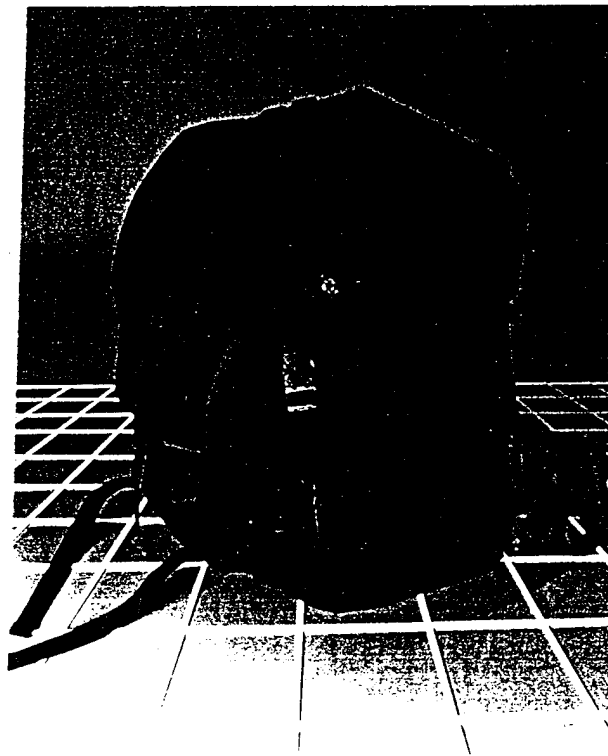


Figure 3. Advanced combined Medical Bag and Rucksack Shown as Single Component Item with Medical Rucksack Internalized

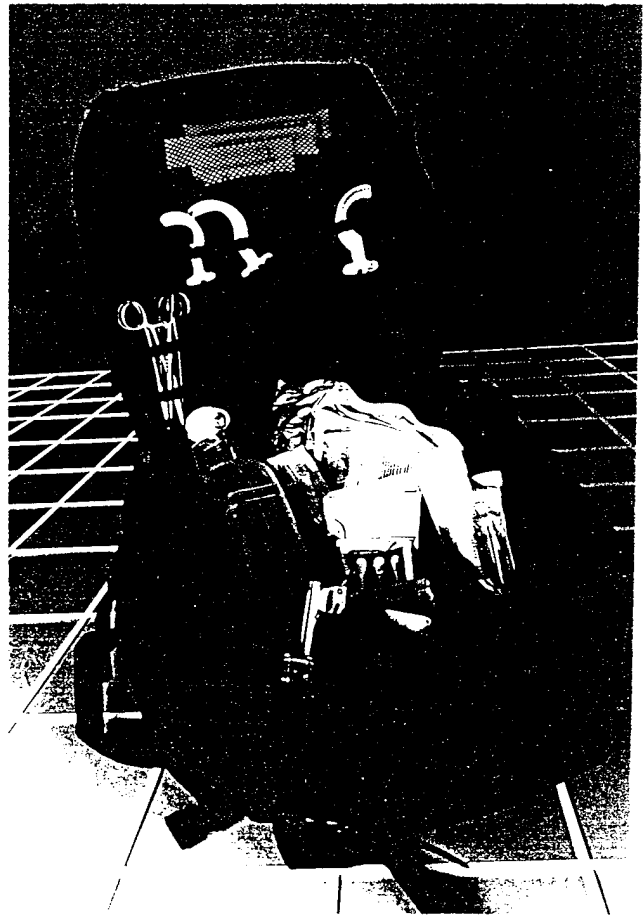
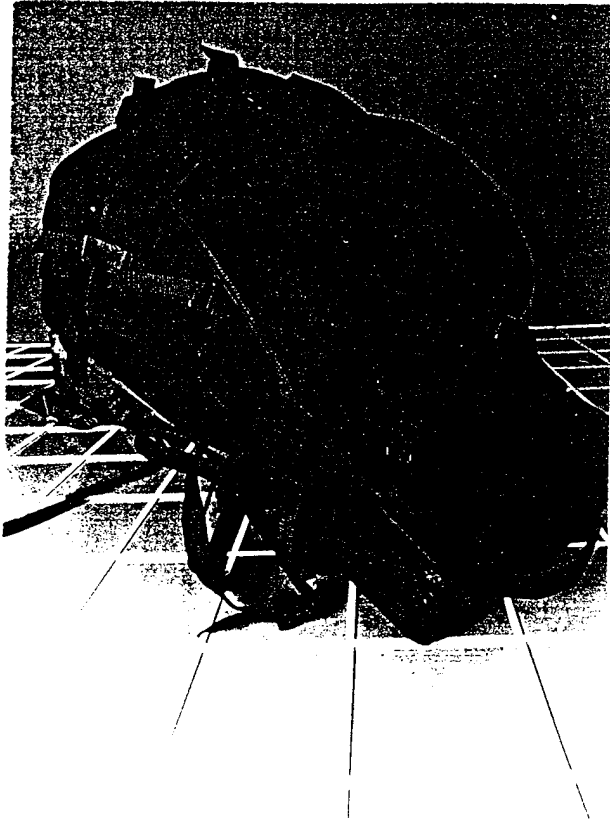


Figure 4. a) Medical Component Being Removed from Rucksack b) Internal Component Displayed

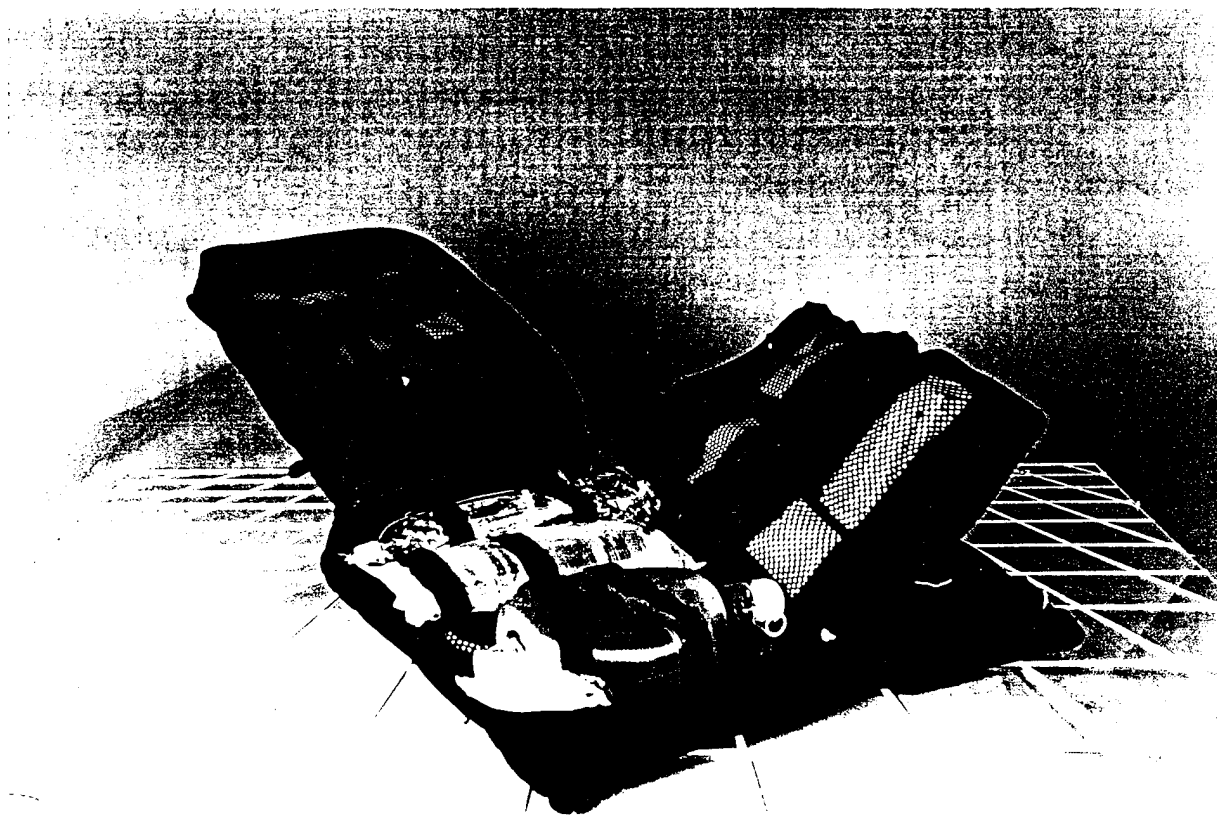


Figure 5. Lightweight Deployable Field Medical Bag for Advanced Operations

CRICOTHYROIDOTOMY SET

Initially an assessment was performed looking at those factors that cause failure in performing a cricothyroidotomy. A cricothyroidotomy is performed in the field to establish an airway in an individual who has either had severe trauma to his upper airway making routine endotracheal intubation difficult or has had at least three attempts at the placement of an endotracheal tube without success. The concept is in providing adequate ventilation to the severely injured soldier as the first component of ATLS is **Airway**. This airway establishment needs to be accomplished within a three to four minute time frame as secondary hypoxia to the brain and heart occurs in this time frame.

It is an invasive procedure that is infrequently performed at the medics level, and is usually accomplished by the physician or rarely the physician's assistant. It necessitates the placement of a breathing tube through the soft tissue of the neck into the trachea. If 15-20% of trauma victims die of airway failure, this is a procedure that would not uncommonly be performed by the medic in the advanced management of the trauma casualty and airway establishment maybe one of the simplest areas in which an improvement in morbidity and mortality may occur.

An initial assessment of three standard FDA approved devices was performed in the laboratory to include the NU-TRACH_{TM}, PERTRACH_{TM}, and the Cook Emergency Cricothyroidotomy Set _{TM}. This assessment involved ease of placement, training issues, potential complications and reproducibility of task completion. The Cook Cricothyroidotomy Set (Figure 6) was noted to be objectively the most compatible with minor modifications to technique and training in the pre-assessment of the options available.

This device was procured from Cook and evaluated in the vivarium at Balboa Naval Hospital by utilizing medics training at the SEAL medics course on swine. A one hour lecture was given the night before the lab and an actual demonstration in the animal lab preceded attempts at placement.

Approximately 28 students were given the opportunity to perform the catheter placement and were allowed a maximum of three attempts. The results revealed that 15/28 (54%) were successful on the first attempt, 25/28 (89%) on the second and 27/28 (96%) were successful in controlling the airway by the third attempt. No attempt was made to record the time it took to control the airway during this initial evaluation. There were no significant complications other than the inability to cannulate the airway. However, recognized complications include bleeding, pneumothorax and potential trauma to the thyroid.

On a scale of 1-10 with 10 being the best score. A review of the product by the medics revealed:

- usefulness(10/10)
- ease of training(10/10)
- ease of task performance (9/10)
- relevance to practice (10/10)

This review revealed the Cook Cricothyroidotomy set to be an acceptable and trainable technique for utilization in the far forward area. More importantly it is a task that can be mastered by the medic with relatively little additional training.

A work group with Cook has begun to assess the feasibility of further refining the cricothyroidotomy set as a single puncture item and incorporating the guide wire which makes the system a modified Seldinger technique into the component item. This would vastly improve the product at this time. It would decrease by at least two steps the placement of the cricothyroidotomy in the injured soldier.

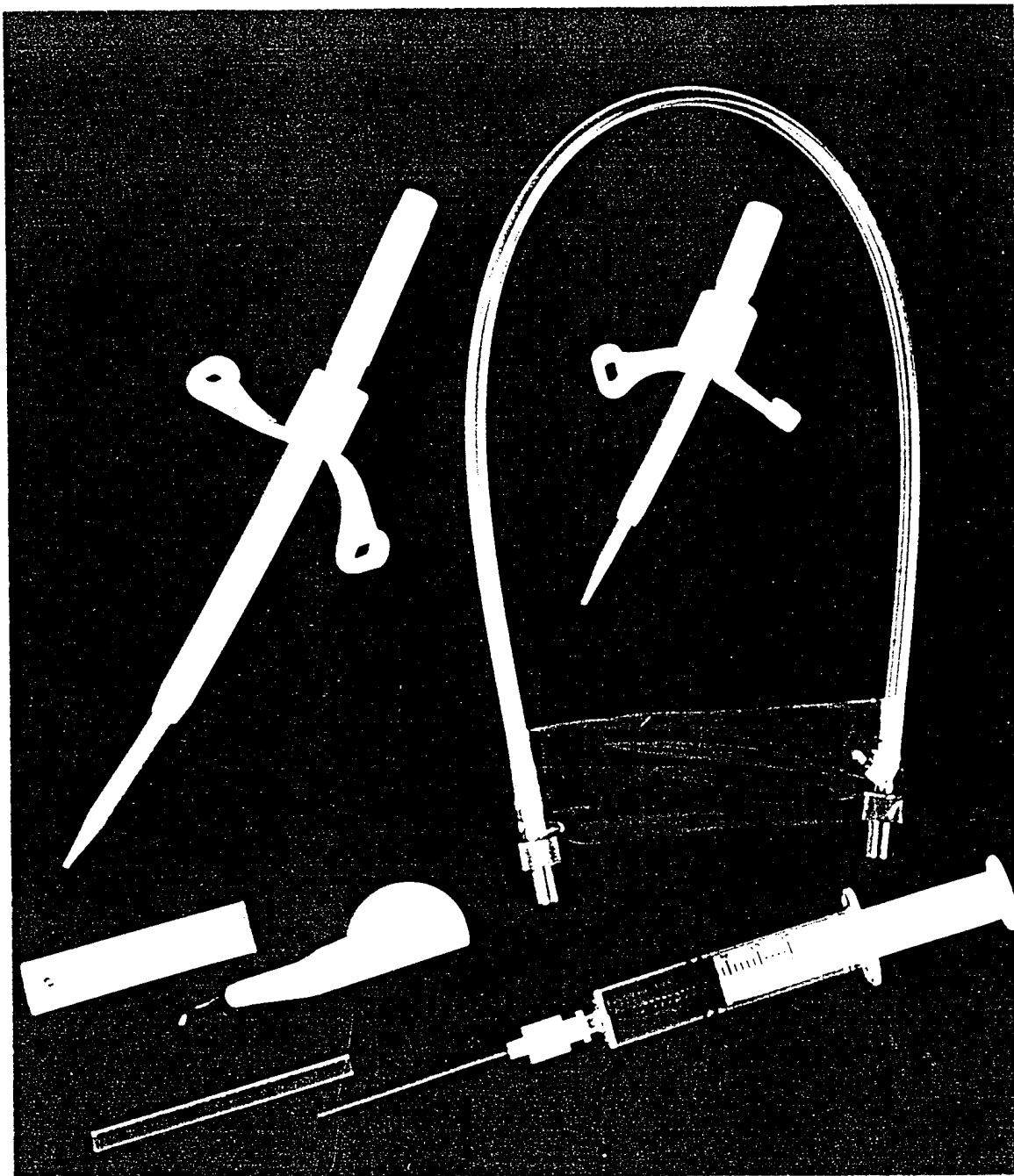


Figure 6. Cook Cricothyroidotomy Set

THORACOSTOMY SET

The recognition of a tension pneumothorax is often very difficult in the critically injured individual. However, if a pneumothorax is not treated, even a relatively stable trauma may rapidly decompensate and suffer severe consequences. The treatment is to relieve the air that is trapped under pressure in the chest before deleterious physiologic complications. This necessitates the placement of a device connecting the pleural space with the external environment.

The placement of a needle is the simplest method to relieve the tension pneumothorax. While this temporizes the injury, during the evacuation of the injured soldier the air may recollect or the potential for a hemothorax may develop. The standard trauma training necessitates the placement of a chest tube into the pleural space after needle decompression. This then necessitates the use of suction and the supporting equipment. Chest tube placement is difficult, time consuming and potentially deleterious at the corpsmen level.

The development of a device that: 1) is easily placed 2) does not require suction during transport 3) allows drainage of blood or accumulated fluid 4) is secure 5) and is portable.

The Cook Thoracostomy Set (Figure 7) with minor modifications met these requirements. The modifications included the development of a fixing device or pad to attach the needle to the chest wall, addition of a three way stopcock to allow for fluid drainage and refinement of packaging to allow for easy portability.

The Cook Thoracostomy Set was tested in animal models at the animal facility at Balboa Naval Hospital with 25 medics in attendance. A lecture regarding device placement lasting 90 minutes was completed the evening before the lab. A single demonstration in the lab was accomplished that morning. Each corpsman was then assessed on time to acquire task, ability to perform task, and number of attempts until successful completion.

The results for 23 soldiers reveal that 15/ 23 (65%) were successful on the first attempt, 22/23 (96%) were successful by the second attempt and after three attempts 23/23 (100%) were able to reduce the pneumothorax. The mean time to procure relief of the pneumothorax after recognition was 50 seconds.

The product assessment on a scale of 1(poor) - 10 (excellent) revealed the following information:

- Training 9
- Usefulness 10
- Ability to Acquire Skill 9
- Transportability 10
- Relevance 9

The overall approval of this product from both a successful skills acquisition to acceptability by the end user was outstanding.

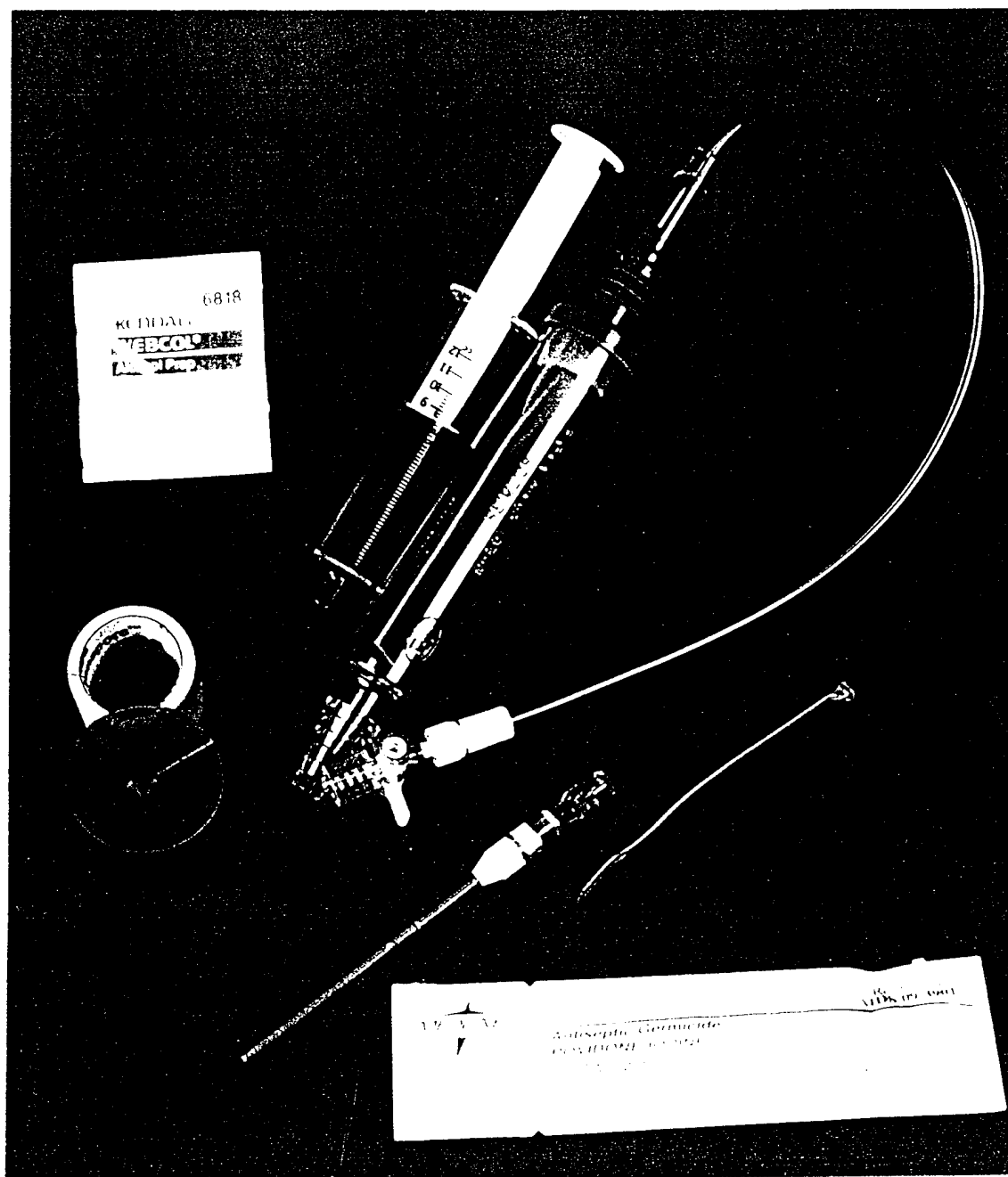


Figure 7. Cook Thoracostomy Set

PORTABLE MONITORING SYSTEM

In order to begin assessing the development and training issues involved with portable monitoring equipment. It was essential to determine what physiological parameters need to be monitored. A survey was conducted among transport physicians, nurses and paramedics in regards to the essential parameters that need monitored in the critically injured trauma patient. The results revealed that:

- Oxygen Saturation (Pulse Oximetry)
- Blood Pressure
- Heart Rate
- Electrocardiogram (EKG)
- Temperature

These five parameters in the order presented were determined to be essential monitors of stability during transport or evacuation. Other items include on the survey included capnography, arterial pressure monitoring and respiratory rate, While these were felt to be valuable they were not essential for transport. Also the ability to place invasive arterial monitoring in the field would be somewhat limited.

A portable device with the above characteristics was sought and the PROPAQ(Protocol Systems, Beaverton, OR)(Figure 8) was found to meet the requirements. The physical characteristics of the PROPAQ include:

- Dimensions: Height 6.8 in; Width 8.2 in.; Weight 10-11 lbs.
- Operating Temperatures: 5°C to 40°C
- Operating Humidity 35-85%
- Operating Altitude -2,000-15,000 ft.
- Operating Time - 4.3 hours (Sealed Lead Acid Battery Pack) *
- EMI: MDS-201-0004 (emissions)
- Water Resistant
- Rechargeable Battery Pack

* The battery time is variable and can be extended up to 24 hours depending on the operational features chosen. This assumes worst case scenario with frequent non-invasive blood pressure and updates.

The device displays continuously: EKG, SpO2, and can cycle for blood pressure using oscillometric blood pressure monitoring at up to 1 minute intervals. With an upgrade of the module an end-tidal CO2 and invasive pressure monitors can be included. It is flight certified and can be converted to power through an adapter to any current.

This device in the basic configuration described above was forwarded to Coronado NAS for testing in the SEALS medic course. Prior training for each individual included a lecture with hands on demonstration provided by the manufacturers representative. This was accomplished under adverse conditions in a field like scenario. Comments and assessment of training was accomplished as previously noted.

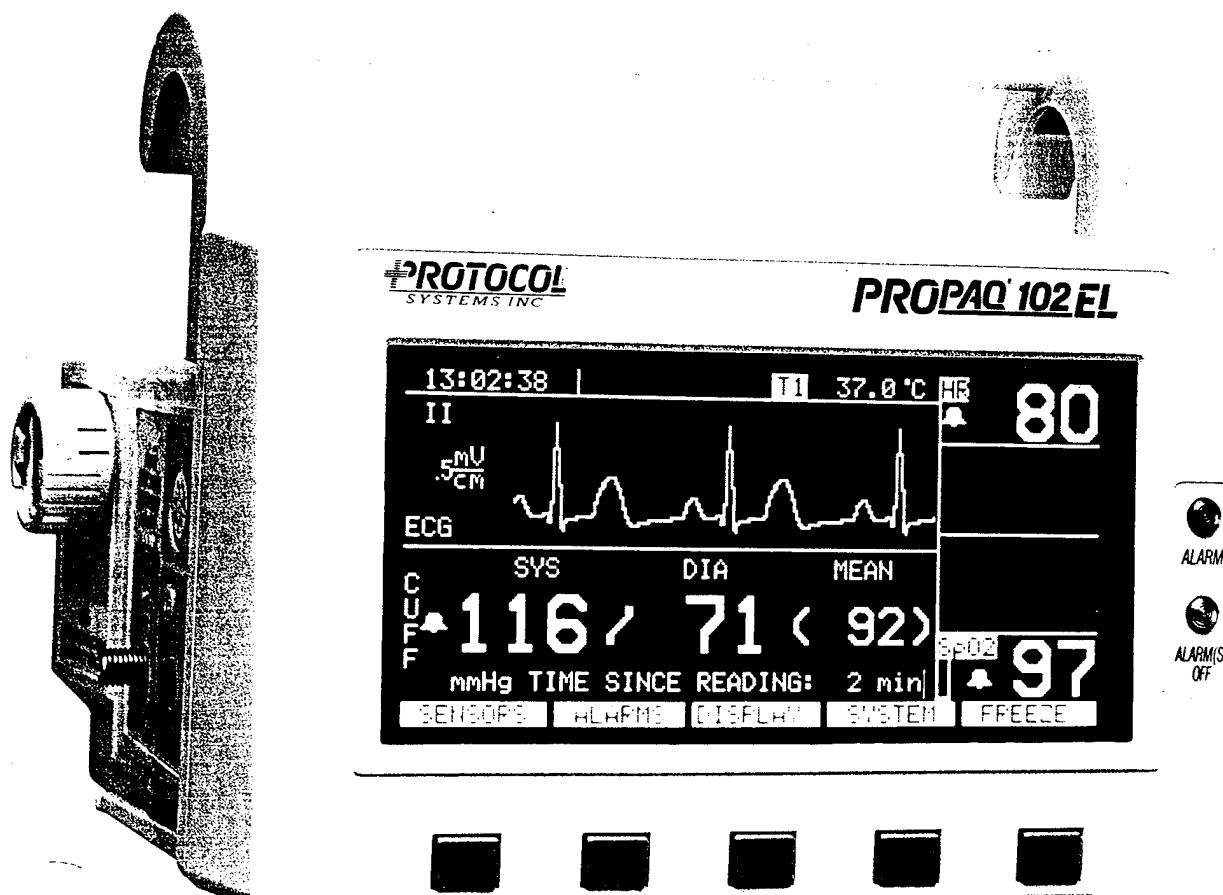


Figure 8. PROPAQ Advanced Non-invasive Monitoring Set for Transport of the Injured Soldier

TRAINING- The ability to place the appropriate monitors and record, acquire and be able to transmit or report the data including trend monitoring capabilities was accomplished in approximately 50 minutes by the 24 individuals. There was no difficulty encountered in data retrieval under the most adverse conditions noted and overall the device was well accepted as a monitoring device in the stabilized or transport area.

The medics felt that overall it was too large for standard operational use unless it would not be carried or would be available either in the transport craft or vehicle. The overall monitor displays, data display and ability to analyze data was overwhelmingly regarded as good after review. There was some question as to how "water resistant" the device was and these comments were forwarded to the manufacturer.

LOCATION- The severely injured soldier would still necessitate some level of monitoring. However, after field assessment. It was noted that the PROPAQ even in its' stripped down version was still too large to include as part of the carried gear. However, for transport and in a stabilized environment the appropriateness of this level of monitoring was appropriate.

CONCLUSION

The responsibility for delivery of advanced resuscitative and early definitive care in the stabilization of the severely injured trauma patient in the military will likely remain in the hands of the medic. By providing the medic with the essential advanced devices, knowledge and technical skills needed to perform those life saving procedures can only enhance survivability. When designing new techniques, devices or procedures, the skill level, input and end user of that product should be involved from the initiation of the project.

The four devices described above have clearly benefited from that input. With minor modifications suggested by the user community and additional evaluation, these products should be considered acceptable solutions to enhancing the medics capability to provide enhanced resuscitative care on the modern battlefield.